REMARKS

Upon entry of the amendments, claims 38-60 and 66-68 are pending in the application. Claims 38 and 67 are amended, and claims 61-65 are canceled. Basis for the amendments can be found on page 34, lines 9-16, of the current specification. Therefore, the amendments do not introduce any new matter within the meaning of 35 U.S.C. §132. Accordingly, entry of the amendments is respectfully requested and allowance of this application earnestly solicited.

35 U.S.C. §103(a) REJECTION

Claims 38-60 and 66-68 stand rejected as being unpatentable over U.S. Patent No. 4,863,743 (Hsiao) in view of U.S. Patent No. 5,567,439 (Myers) and U.S. Patent No. 4,764,375 (Paradissis). In support of the rejection, the Examiner states:

> The rejection of record is maintained; see below. The instant claims are silent as to the Flavoring and taste masking agents, animal, particles, and extended release coating. Hsiao can be construed as meeting them, with the sugar, flavorant and taste masking agent, used in coated prior art tablets (col. 7, last paragraph, top, and col. 8), if flavor is deemed a parameter of concern. In all other respects, Hsiao provided coated Kcl (Example 1) granules, with microcrystalline cellulose and crospovidone, PEG, as tablets, Example 2, adds magnesium stearate; similar to applicants Na-stearyl fumerate of Example 1; the tablets are the instant formulations of 20 mEq of Kcl. However, 68%-86% Kcl is shown (column 7). Disintegration occurs within 5 minutes (column 5, lines 19-24) with sustained release leading to 909% Kcl released after 6 hours (Tables I, II).
>
> The components providing for the dispersing and releases periods as instantly claimed are thus Hsaio.
>
> Administration as a liquid was seen as placing in water, or on an aqueous food, which is then administered to those having swallowing difficulties (col. 5) line 65- line 7, col. 6). Stirring and Mixing if desired, is known - it was used in preparation (Example 2) thus would be within the purview of one to perform, if the desired dissolution period shorter than produced by simply placing in water. This is the instant invention, absent a clear showing of coloring and flavorant. Paradissis is evidence it was well known at the time of the instant invention, to add colorants and flavorants even to taste-masked coated actives (col. 2), including Kcl (claim 7), for particle dispersion in liquids. Further, multi substance preparations are also known (col. 2, lines 35, 360). Myers discloses examples of Flavorants (col. 9 top through line 7, col. 10 and colorants (col. 10, lines 28-33) useful in drug tablet (col. 7, lines 47-49) compositions.
>
> It would have been obvious to a person of ordinary skill in the art at the time invention was made, desiring to utilize Hsiao's Kcl tablet in a form to provide enhanced palatability, disperability and sustained release, as taught by paradissis and exemplified by Myers.

All critical elements of the instant are disclosed. The amounts, dosage regiments and mixing times are result effective parameters chosen to obtain the desired effects. It would be obvious to vary the ingredients to optimize the effect desired, depending upon the intended active agent, concern for side effects, species, age, sex, dosage, minimization of number of applications, patient acceptance for example.

The instant invention provides well-known old art recognized effects, applied by well known art-recognized methods to achieve the desired effects.

Applicant has not provided any objective evidence of criticality, nonobvious or unexpected results that administration methods with the particular ingredients' or dispersion times provides any greater or different level of prior art expectation as claimed, and the use of ingredient for the functionality for which they are known to be used is not basis for patentability.

Applicant's argument filed 10/23/03 have been fully considered but they are not persuasive. Applicant argues.

Hsiao teaches tablets which are sweetened. Flavorings and tastemasking are not taught. Further, Hsiao teaches, in Table I, that the controlled release is such that at least 91% of the active agent is released within 6 hours. As such, the tablets of Hsiao would result in a tablet, which was not as palatable as the one utilized in the present methods and which release the active over a shorter period of time.

The secondary references do not remedy these deficiencies. Myers teaches tastemasking via an effervescent agent, which is outside the scope of the present invention. The present invention specifically avoids effervescent technologies.

Paradissis is not concerned with the overall design of a method to enhance patient compliance but rather a specific form of tastemasking of hydrophilic active agents.

Examiner finds "sweetners" absent specification of flavoring agent, meets this criteria, and also meets the new taste masking, also not specified, criteria. As to lacking palatibility in comparison, we see no such claim to this condition, while the shorter period of time is still within the instant invention as it is claimed agreed, the secondary references teach effervescence, but there is no proscription to one of ordinary skill in the art of administering therapeutics to a patient, to look at only selected references directed at improving patient compliance. Note that the methods as claimed is directed to animal oral dosing; patient compliance is not readily seen, as self dosing, or as selecting, ordering, labeling, appropriate dosage, but rather patient acceptance upon human intervention, consisting of human administering the dosage. As to myers, myers is directed to controlled

> release systems (col. 1, lines 12-14) col. 4, lines 6-20) which includes instant and/or delayed or sustained release. The example is not to effervescent tablets. Neither does Paradissis require effervescence.
>
> We fail to discern any distinction between the instant claimed invention and what one of ordinary skill in the art would provide, with the background, as represented by the cited references, of the means of enhancing acceptability by an animal of a therapeutic composition.

Applicants respectfully maintain the traversal of record. The claims are currently amended to define the present invention and more clearly explain its superior qualities over the compositions contained in the cited references.

The present invention is drawn towards a method of patient compliance by administering the non-effervescent flavored suspensions of the present invention. The method utilizes suspensions which are flavored, tastemasked and have a controlled release profile of about 2 to about 48 hours, and which **have a viscosity of about 25 cp to about 75 cp**. The claimed viscosity produces a uniform suspension, which increases the ease of administration to a patient.

As such, the present methods may have improved palatability to a patient and reduce the unpleasantness associated with administration. Further the present methods may reduce the number of doses required due to the controlled release profile.

Hsiao teaches sweetened tablets, but does not teach that viscosity is a critical aspect. In contrast to Hsiao, the viscosity of suspensions of the present claims makes uniform suspensions thereby increasing ease of administration. Further, the present invention is

to be administered in a flavored suspension. Hsiao does not teach that a suspension would be formed if the subject tablets were placed in water. Hsiao also does not teach what the relative taste of the tablets placed in water would be. Hsiao is only concerned with the merits of various forms of administration with respect to various types of patients. Sweeteners are taught, but flavorings and tastemasking are not. Further, Hsiao teaches, in Table I, that the controlled release is such that at least 91% of the active agent is released within 6 hours. As such, the tablets of Hsiao would result in a tablet, which is not as palatable as those of the present methods and which releases the active over a shorter period of time.

The secondary references do not remedy these deficiencies. Myers teaches use of an effervescent agent for tastemasking, which is specifically outside the scope of the present invention. See present specification, page 36, lines 12-14. Further, Myers does not teach the criticality of viscosity. There is no disclosure in Myers which would lead one of skill in the art to adjust the viscosity to acheive the present invention.

Paradissis likewise fails. Paradissis is directed to a drug delivery system for use with bad tasting drugs that can be suspended in a liquid carrier. The system is formed by pulverizing potassium chloride and dispersing it in wax. See col. 1, line 64 through col. 2, line 2. The suspensions of Paradissis are formed by producing a product with a density of approximately 1 if it is to be placed in water. Col. 2, line 5-9. Further, the tastemasking coating of

Paradissis is resistant to forming a suspension (col. 2, lines 18-19) and must be modified with surfactants or other surface modifiers if they are to do so.

The present claims have been amended to cover a flavored suspension having a viscosity of about 25 cp to about 75 cp. As noted above by Applicants, the uniform suspensions produced by the claimed viscosity aids in administration. Paradissis does not teach that viscosity is a critical aspect. Further, Paradissis relies on the density of its products and the addition of surfactants to produce pellets which form a suspension. The present invention is comprised of coated, rather than dispersed, particles. These particles form a flavored suspension, which is achieved by modification of the liquid media. See, specification page 34, lines 1-8.

For these reasons, Applicants respectfully request that the Examiner reconsider this rejection and earnestly solicit allowance of the pending claims.

CONCLUSION

If the Examiner has any questions or wishes to discuss this matter, he is welcomed to contact the undersigned attorney.

Respectfully submitted,
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